

REMARKS/ARGUMENTS

Claims 1-51, 53, and 56-63 are pending. Claims 1, 2, 6-8, 11-13, 15, 22-25, 29-33, 35, 36, 40-42, 45-47, 49, 53, 59, 60, and 63 were rejected, with all other pending claims having been withdrawn pursuant to a prior Election of Species Requirement.

For the reasons set forth below, Applicants believe that the rejection of independent claims 1 and 35 should be withdrawn. Therefore, Applicants believe that all pending claims should remain in the application and that the provisional restriction in view of the Election of Species Requirement should be withdrawn.

Independent claim 1, as well as various claims dependent thereon, have been newly rejected over the combination of Sharkey '087 in view of newly-cited Goltzer '305. Such rejection is respectfully traversed.

Sharkey '087 teaches a catheter for accessing an intervertebral disk. The catheter may include a "functional element for performing a function" adjacent some selected portion of the disk, such as delivering energy, adding material, removing material, or the like. As described, for example, at Col. 12, lines 51-62, the catheter may be used to deliver substances, such as "medicaments for the relief of pain associated with a fissure or herniation . . ." Nowhere, however, does Sharkey '087 ever teach that the catheter have a balloon or any other means for immobilizing a distal end of the catheter within the disk.

The Examiner recognizes that deficiency and relies on Goltzer '305 to teach anchoring the distal end of the Sharkey catheter within the disk. Specifically, the Examiner asserts that Goltzer teaches "a method for retaining an epidural catheter comprising the steps of inflating a balloon to anchor the distal end of the catheter in the desired location so that the catheter remains securely fixed in the desired location (Abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to include the step of anchoring the distal end of the catheter in place as taught by Goltzer so that the patient can move without dislodging the catheter."

Applicants respectfully disagree with such an assertion. As the Examiner is undoubtedly aware, the intervertebral disk space and the epidural region of the spine are entirely

different regions and structures. The epidural space is a potential space between the bony and ligamentous elements forming the outer borders of the spinal canal and the dura mater surrounding the spinal cord and nerve roots that run with it. The intervertebral disk space, in contrast, is the compliant inner core of the intervertebral disk, also referred to as the nucleus pulposus.

The Examiner's attention is directed to Figs. 1 and 2, attached as Exhibit A, which illustrate the anatomical relationship of the intervertebral disk space and the epidural region. These two distinct regions are clearly physically remote, as the intervertebral disk space is much deeper, and are also structurally and functionally distinct. The epidural space is a potential space surrounding a spinal cord and nerve roots, while the intervertebral disk is a structural component of the patient's spine which carried significant axial loads as the patient moves about.

Because of the anatomical distinctions between the intervertebral disk space and the epidural region, Applicants do not understand why one skilled in the art would look to the teachings of Goltzer '305 to modify the methods taught in Sharkey '807. In particular, Goltzer '305 describes the use of a balloon to anchor a catheter in the potential space of the epidural region. The need to anchor the catheter is apparent since the "potential space" is just that, a region free from structure where the distal end of the epidural catheter would flop about unrestrained in the absence of the balloon or some other anchoring mechanism. Moreover, such unconstrained movement of the distal end of an epidural catheter would risk traumatic injury to the spinal cord and nerve root, both of which are unacceptable possibilities.

In contrast, there is no apparent need to anchor the distal end of the catheter of Sharkey '087 in the intervertebral disk. In the first place, the disk is a filled structure where the distal end of the catheter would not be expected to move freely or to flop about. Moreover, Sharkey does not disclose that the catheter is ever to be used on patients who are mobile or expected to move about. For all of the procedures described in Sharkey, it would be expected that the patient would be immobilized, thus teaching against any need to provide for a balloon or any other anchor on a distal end of the catheter to hold the catheter in place within the disk.

Applicants recognize that balloon anchors have been used in medical procedures for decades. Applicants further recognize that an anchor on an epidural catheter is necessary for

all the reasons discussed above. Applicants disagree with the Examiner, however, that it would have been obvious in view of Goltzer for other balloon-anchoring devices for that matter to modify the Sharkey device and method to rely on a balloon or other anchor because there is nothing in the Sharkey teachings which would suggest any benefit to providing such a balloon.

In contrast, the methods of the present invention contemplate that the patient will be changing positions, either for diagnostic or other purposes. To have the patient change positions with a catheter in the disk space is nowhere contemplated or suggested by the teachings of Sharkey '087 where all procedures appear to be performed while the patient is immobilized.

The Examiner's combination of Goltzer '305 with Sharkey '087 is nothing more than hindsight reconstruction. The rejection, in essence, relies on nothing more than the assumption that since anchored balloon catheters exist, it would therefore be obvious to modify the catheter of Sharkey to have a balloon. Such an argument does not meet the requirements of 35 USC §103.

For these reasons, it is believed that independent claim 1 as well as all claims dependent thereon are in condition for allowance. Independent claim 5, the only other pending independent claim, was rejected over the combination of Sharkey '087 and Goltzer '305, as discussed above, further in combination with Sluijter '739.

The Examiner relies on Sluijter as "inherently" teaching that a "patient has assumed a position where spinal pain is experienced because that would be a necessary step in determining the fact of the treatment...on the pain experience." Applicants respectfully disagree with this characterization.

While Sluijter '739 does teach that an anesthetic might be injected through a needle 802 which is being used to measure electrical impedance within a disk prior to heat treatment, it is in no way inherent that the patient has assumed a position which would be expected to cause pain. The teachings of Sluijter '739 are perfectly consistent with a patient lying on a treatment table, particularly since the treatment will require not only insertion of the treatment canula and needle, but also placement of an external electrode pad, e.g. pad 9 as shown in Fig. 1.

Thus, Applicants believe that independent claims 1 distinguishes the combination of Sharkey '087 and Goltzer '305 for all the reasons set forth in connection with claim 1, and further that the reliance on Sluijter '739 does not teach the further limitation in claim 35 that the patient assumes a position in which substantial spinal pain is experienced. For these reasons, Applicants believe that independent claim 35 as well as all claims dependent thereon are clearly patentable over the cited art.

CONCLUSION

If for any reason the Examiner believes that a telephone conference would in any way expedite prosecution of the subject application, the Examiner is invited to telephone the undersigned at 650-326-2400.

Respectfully submitted,

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